REMARKS

Claims 1-17 are currently pending in this application. Claim 17 is amended and claim 18 is cancelled. No new matter is added.

It is submitted that the claims, herewith and as originally presented were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112, and are not narrowing amendments. Rather, any amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for any amendments is found throughout the specification and from the pending claims.

The Office Action required restriction from among the following Groups under 35 U.S.C. §121:

Group I: Claims 1-16, drawn to a composition comprising an NMDA receptor antagonist and an analgesic and methods of topically applying the composition; and,

Group II: Claims 17-18, drawn to a method of topically applying one analgesic that functions through an opioid receptor and sytemically or intrathecally administering a second analgesic that functions through an opioid receptor.

Group I is elected with traverse for further prosecution in this application. As a traverse, it should be noted that claim 17 is now drawn to the same subject matter as the Group I claims, *i.e.* a method of topically applying a composition comprising an NMDA receptor antagonist and an analgesic.

As stated on page 2 of the Office Action, the technical feature linking claims 1-16 is the composition comprising an NMDA receptor antagonist and an opioid analgesic. This technical feature is present in claim 17, forming a single inventive concept. Therefore, unity of invention exists and the pending claims 1-17 should be examined together in this application. Further, there is no undue burden on the Examiner to search and examine all of the claims as a single group.

The Office Action also calls for an election of species on page 3, alleging that the species lack unity of invention. The species identified are an NMDA receptor antagonist, a first

analgesic that functions through an opiate receptor, a pharmaceutically acceptable topical excipient, and a second analgesic that functions through an opiate receptor. Members of each species were not identified in the Office Action. Ketamine as the NMDA receptor antagonist, morphine as the first analgesic and an aqueous solution comprising ethylene oxide as the topical excipient are hereby elected, with traverse. A second analgesic does not need to be elected, as the claims of Group I were elected.

PCT rule 13.1 and 13.2 are followed for applications filed during the national stage as a Designated or Elected office under 35 U.S.C. § 371 without regard to the practice applied to national applications filed under 35 U.S.C. § 111 outside of the PCT (MPEP 1850). It has already been determined during the international stage that the pending claims do not lack unity of invention. Further restriction among species is therefore unnecessary in view of the finding by the international searching authority and Examiner during the international stage.

It is respectfully requested that the species election requirements be favorably reconsidered and withdrawn, since the species are each related to one another and directed to the same inventive concept—as determined during the international stage—and can be searched and examined simultaneously without placing undue burden on the Examiner.

In the instant case, there is a disclosure of relationship between the claimed species. Under PCT Rule 13.1, the members of the species are clearly linked to one another to form a single concept. The fact that a species is identified as, for example, an NMDA receptor antagonist undermines the argument that there is no technical relationship between the members of the group. Unity of invention, therefore, exists.

The PCT Rules and the sections of 37 CFR related to unity of invention in national phase applications are silent on the topic of species election. Turning to MPEP 808.01(a) on this point, it is stated (in bold print), "[e]lection of species should not be required if the species claimed are considered clearly unpatentable (obvious) over each other."

It is Applicants' understanding that, upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all of the limitations of an allowed generic claim, as provided by 37 C.F.R. 1.141. It is also understood that the Examiner can broaden the search to include other species, e.g., upon determining that a species is allowable, or as discussed herein, when there is a relationship among the species and/or number of species is not too great.

In this regard, M.P.E.P. § 808.01(a) states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate. Moreover, MPEP 803.02 specifically provides that members of a claimed *Markush* group must be searched and examined together, if they are not too many in number.

Examination of the generic claims, without election, does not impose a serious burden on the Examiner. An examination of claims wherein the analgesic is morphine, for example, would inevitably encompass a search that included ethylmorphine, hydromorphine, oxymorphone and the other recognized members of that group. Especially with respect to the recitation of a pharmaceutically acceptable topical excipient, it would be routine and well within the skill of one in the art to choose an acceptable excipient. No election among excipients is therefore required.

Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional or continuing applications filed). Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action and there are relationships between all of the pending claims. Indeed, the search and examination of each Group is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner. All of the foregoing, therefore, mitigate against restriction.

CONCLUSION

In view of the foregoing, reconsideration and withdrawal of the requirements for restriction and election of species are respectfully requested.

It is believed that no fee is due for entry and consideration of this paper, however, please charge any required fee or credit any overpayment of fees to Deposit Act. No. 50-0320.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

17. (Amended) A method of providing analgesia to a mammal comprising topical administration of a tolerance-attenuating or preventing dose of at least one NMDA receptor antagonist and at least one analgesic that functions through an opiate receptor prior to, concurrently or following systemic or intrathecal administration of a second analgesic that functions through an opiate receptor.